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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,847	12/08/2000	Liang C. Dong	ARC 2644 R1	2029

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/23/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,847

Applicant(s)

DONG ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Acknowledgement: Receipt of Petition under CFR 1.137(b), Request for Reexamination, Information Disclosure statement and Power of Attorney; all filed January 5, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

3. The instant claims recite "up to 60% and therefore include 0% antiviral agent. Accordingly, it is unclear how an effective dose of an antiviral agent can be administered without said drug. For purposes of examination, the claims are interpreted as being capable of releasing a drug with the instant parameters.

Claim Rejections - 35 USC § 103

4. Applicant's remarks filed April 16, 2003 have been considered but are not found persuasive. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (US 5, 952,004; hereafter Patent '004) in view of Eckenhoff et al (US 4, 692, 326; hereafter Patent' 326) or Rudnic et al (US 5, 952, 004; hereafter Patent '004) in view of Eckenhoff et al (US 4, 800, 056; hereafter '056).

7. Patent '004 teaches stable, liquid, microemulsion drug delivery systems for poorly soluble active agents. These formulations are administered in capsules such as controlled release capsules and are liquids having the formulation as the instant claims (i.e. self-emulsifying formulation). Patent '004 does not teach how the capsules are configured to release the formulation over the controlled period of time.

8. Patent '326 and Patent '056 both teach controlled release oral capsules comprising liquids that provide sustained release for a period of 1 hour to months. In other words, Patent'326 and Patent '056 teach tailoring of the dosage form in accordance with the ingredients of the capsules. Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to adjust the amounts and types of fluid imbibing and retaining polymers for forming the hydrophilic, expandable push member, osmotically effective compound, swellable, expandable

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polymer in accordance with the semipermeable wall and inner member or layer to achieve the instant dosage form configuration with the motivation of providing controlled release of the formulation.

9. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the liquid formulation of Patent '004 with the dosage form of Patent '326 Or Patent '056 and the motivation of providing a prolonged release formulation of the liquid active agent that is stable.

Response to Arguments

10. Applicant's remarks filed April 16, 2003 have been considered but are not persuasive. Applicant argues that a prima facie case of obviousness has not been presented since the references do not specifically set forth the release profile as currently claimed. This argument is not persuasive as it is the position of the Examiner that combination of the references teaches one skilled in the art at the time of the invention that the release profile can be "tailored" through adjustment of the ingredients in the capsules. In the prior art cited, it has been considered that Figure 10 of Patent '056 and Figure 10 of Patent '326 both appear to show that not more than 30% of the formulation is released within the particular required periods.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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